K131961

HEINE

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510(k) Summary of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act, HEINE Optotechnik GmbH & Co. KG herewith submits a Summary of Safety and Effectiveness.

Submitter Information:

HEINE Optotechnik GmbH & Co. KG
Kientalstr. 7
82211 Herrsching
Germany
Registration Number: 1000379039
Owner/Operator Number: 9003020

DEC 04 2013

Official Contact Person:

Mr. Manfred Bartsch-Tittmann
Director Regulatory Affairs
HEINE Optotechnik GmbH & Co. KG
Phone: +49 8152 38 0

US Agent (Contact):

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10 Innovation Way
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Date Prepared: June 20th, 2013

Device(s) Identification:

Device Trade Name: HEINE BETA 200® Ophthalmoscope
Common Name: Ophthalmoscope

Classification of the device:

Device Classification Name: Ophthalmoscope
Product Code: HLJ
Device Classification No.: Part 886.1570
Panel: Ophthalmic Devices (86)
Regulatory Status: Class II

Device Description:
The HEINE BETA 200® Ophthalmoscope is a battery powered hand-held device to provide illumination and viewing optics in order to examine the media and the retina of a patient's eye. It consists of an instrument head and a battery handle that can be attached to the instrument head.

Intended Use:
The HEINE BETA 200® Ophthalmoscope is a battery powered hand-held device for medical professionals, containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye.

Predicate Device:

Device Trade Name:	HEINE mini 3000® LED Ophthalmoscope
Applicant:	HEINE Optotechnik GmbH & Co. KG
510(k) No.:	K123587

The HEINE BETA 200® Ophthalmoscope is considered substantial equivalent to the HEINE mini 3000® LED Ophthalmoscope (K123587).
There is no significant difference in intended use or technology.

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	HEINE BETA 200® Ophthalmoscope	HEINE mini3000® LED Ophthalmoscope	**Assessment**
Intended Use	The HEINE BETA 200® Ophthalmoscope is a battery powered hand-held device for medical professionals, containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye.	The HEINE mini3000® LED Ophthalmoscope is a battery powered hand-held device for medical professionals, containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye.	Same (see rational chapter 4)
Type	Monocular	Monocular	Same
Method of operation	Used to examine the retina by an examiner in a specific distance to the eye.	Used to examine the retina by an examiner in a specific distance to the eye.	Same
Illumination type	Halogen filament bulb	LED	Different
Exposure parameters	Emission of 2.5 V + 3,5V halogen bulb	Emission of a white LED	Different[3]
Light output[1]	505 lux (2,5V) / 1180 lux (3,5V)	542 lux	Different[3]
Filter	Blue, Red free (Green)	Red free filter	Same
Service life of illuminant	approx. 45 hours	Unlimited	Different
Diopters	+ 40D to –35D	+ 20D to –20D	Different
Lens power viewing optics	Diopter of used lens in steps: + in 1 D step 1-10, 15, 20, 40 – in 1 D step 1-10, 15, 20, 25, 35	Diopter of used lens in steps: -20, -15, -10, -8, -6, -4,-3, -2, -1, 0, 1, 2, 3, 4, 6, 8, 10, 15, 20	Different

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Light apertures[1]	1) Slit 2) Medium circle with reticle D= 23,2 (=fixation star with polar coordinates) 3) Cobalt blue filter 4) Large circle D= 29,3 (=large spot) 5) Small circle D= 19,2 (=small spot) 6) Hemispot (=semicircle) + Additional Red Free filter BETA200 apertures  Slit, fixation star with polar coordinates, cobalt blue filter, large spot, small spot, hemispot  With red-free filter	small circle D = 13,8 mm large circle D = 27,3 mm semicircle medium circle with reticle D = 23,1 mm	Equivalent
Correction lens adjustable with left/right hand	Yes	Yes	Same
Supply voltage	2.5 V / 3,5 V	2.5 V	Equivalent
Power sources[2]	Battery powered (2 (2,5V) or 3 (3,5V) alkaline cells (size LR6/AA)	2 alkaline cells (size LR6/AA) / HEINE mini 2Z rechargeable battery	Equivalent
Brightness controls	Rotary potentiometer (dimming rheostat)	none	Equivalent
Maximum temperature of parts of the device held by the operator or accessible to the patient	Complies with IEC 60601-1 for temperatures of external surfaces and controls[8]	Complies with IEC 60601-1 for temperatures of external surfaces and controls[4]	Equivalent

Flammability of materials	Low probability. All measures have been taken to use self-extinguishing materials. The system is illuminated using a Halogen bulb and all materials used in the vicinity are specially designed to safely operate in high temperature environments.	Low probability. All measures have been taken to use self-extinguishing materials. The system is illuminated using a 3W LED lamp and all materials used in the vicinity are specially designed to safely operate in high temperature environments.	Equivalent
Note 1: Measurements taken 200 mm from output (direct ophthalmoscopes), large circle aperture Note 2: All power sources comply with the relevant standard of IEC 60601-1 and IEC 60601-1-2.			
Note 3: The XHL bulb is considered to be acceptable because of the following aspects: a) The emission spectrum and the emission intensity of LED bulbs remains constant with respect to fluctuations of the power supply and are constant over its whole lifetime. Is the battery voltage decreasing, the LED color temperature does not change, which is the case with halogen. b) The color reproduction of the HEINE mini3000® LED Ophthalmoscope (color temperature 4000K) is comparable to that of a halogen bulb. c) XHL has lower light output than LED. The maximum exposure time is specified in the instructions for use.			
Note 4: Chapter 17 of this submission contains the corresponding test report No. E256178-A18-CB-1. Please refer to clause 42 of test report E256178-A18-CB-1 for further details.			

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Summary of Non-Clinical Performance Testing:
The HEINE BETA 200® Ophthalmoscope is tested according to the "Ophthalmoscope Guidance" in respect to optical radiation hazard with ophthalmoscopes (ISO 10942). Additionally testing in accordance with applicable requirements of ISO 15004-2 "Ophthalmic instruments – Fundamental requirements and test methods" has been performed.

Conclusion:
HEINE Optotechnik believes that the HEINE BETA 200® Ophthalmoscope is substantially equivalent to the currently legally marketed devices. It does not introduce new indications for use, have the same technological characteristics and do not introduce new potential hazards or safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 4, 2013

HEINE Optotechnik GmbH & Co. KG
Mr. Manfred Bartsch-Tittmann
Director Regulatory Affairs
Kientalstr. 7
82211 Herrsching
Germany

Re: K131961
HEINE BETA 200® Ophthalmoscopes (Models 2.5V and 3.5V)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLJ
Dated: October 10, 2013
Received: October 25, 2013

Dear Mr. Bartsch-Tittman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K131961

Indications for Use

510(k) number (if known):
Device Name: HEINE BETA 200® Ophthalmoscope
Indications For Use:

This instrument is designed for examination of the eye.

BETA handles are designed exclusively for use with medical examination instruments with bulb illumination.

Prescription Use___X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bradley S. Cunningham -S
2013.12.03 12:28:00 -05'00'

Division of Ophthalmic and Ear
Nose and Throat Devices